K101590

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date

NOV 29 2010

June 1, 2010

Manufacturer

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Trade/Proprietary Name:

Xmaru1210P

Common Name:

Digital Flat Panel X-ray Detector

Classification Name:

Solid State X-ray Imager, flat panel/digital imager (21CFR 892.1650, Product code MQB,

Class2)

Description:

Xmaru1210P is a portable digital X-ray flat panel detector which consists of a scintillator directly coupled to an a-SI TFT sensor. It makes high-resolution, high-sensitive digital images. Xmaru1210P is designed specifically to be integrated with an operating PC and a X-ray generator to digitalize x-ray images into DICOM compatible image files for the purpose of diagnostic analysis.

Indication for use:

Xmaru1210P Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. Not to be used for mammography.

Predicate Device:

Manufacturer	: Canon Inc.
Device	: CXDI-50G
510(k) Number	: K031447 (Decision Date – May 21. 2003)

Substantial Equivalence:

VATECH Co., Ltd. considers Xmaru1210P is as safe and effective as the predicated device ,Canon digital radiography CXDI-50G, cleared under the document number K031447 and the performances for both devices are substantially equivalent as indicated in the SSXI non-clinical report of this submission.

The intended use, application and detector type of Xmaru1210P are the same as those of CXDI-50G. However, the differences in the material for fluorescent screen of Xmaru1210P are described below:

.Both Xmaru1210P and CXDI-50G use the same amorphous silicon alley as the sensing means, however, Xmaru1210P uses a different material from CXDI-50G for fluorescent screen which is deposited on the amorphous silicon array. Xmaru1210P uses CsI (Cesium Iodide) with a high X-ray absorption capacity as fluorescent screen. The SSXI test report

shows that Xmaru1210P has a better performance than Canon's CXDI-50G in terms of MTF (Modulaion Transfer Function) and DQE (Detective Quantum Efficiency) performance to result a better resolution, higher exposure sensivity and better image quality as demonstrated in the SSXI Non-clinical and clinical report included in this submission.

The differences in the external dimensions and the weight of Xmaru1210P are as follows:
The external dimensions of Xmaru1210P (422x403x22mm) is smaller than CXDI-50G (491x477x23mm).
The weight of Xmaru1210P (3.4 kg) is lighter than CXDI-50G (4.8 kg).
The physical appearance of Xmaru1210P are different than CXDI-50G.

The indications for use for Xmaru1210P are limited to head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.).

Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1(1995), IEC 60601-1-1 (2001) was performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2 (2001).

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the Submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed.
All test results were satisfactory.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Vatech Co., Ltd. concludes that Xmaru1210P is safe and effective and substantially equivalent to the predicate device as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

VATECH Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Consultant
VATECH America
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SECAUCUS NJ 07094

Re: K101590
Trade/Device Name: Digital Flat Panel X-ray Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 6, 2010
Received: October 8, 2010

AUG 23 2013

Dear Mr. Kim:

This letter corrects our substantially equivalent letter of November 29, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K101590

NOV 2 9 2010

Device Name: Digital Flat Panel X-Ray Detector /Xmaru1210P

Indications for Use:

Xmaru1210P Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. Not to be used for mammography.

Prescription Use ✓ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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